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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,602	02/22/2005	John Hadden	3115.00066	4753

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
01/04/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,602	HADDEN ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 12/2/10 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/10 has been entered.

Claim 24 has been amended.

Claim 24 is pending and is under examination.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,614,504, March 25, 1997.

As set forth previously, The '504 patent teaches a method of enhancing the immune response to a vaccine comprising administering an adjuvant formulation comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP compound, see column 1, 6, 9, and, in particular). The '504 patent teaches administering the IMP compounds to treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent also teaches measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds (i.e. detecting a T cell response, see column 18-19, in particular).

Applicant's arguments filed 9/23/10 have been fully considered, but they are not persuasive.

Applicant argues that the '504 patent only disclosed administering an IMP compound alone, and does not disclose administering a vaccine agent.

The '504 patent teaches in Example 10 that mice are treated with a combination

of squalene and MIMP. Squalene is an adjuvant that enhances the immune response to viral antigens and enhances protection from influenza infection, and can be considered an "anti-viral agent". Furthermore, in Example 10, the mice are also treated with influenza virus in combination with MIMP. As recited in the instant claims, a vaccine agent can be a "virus", as taught in the '504 patent. The '504 patent also teaches that MIMP can be administered in combination with a subinfection dose of influenza virus (i.e. a "vaccine agent") to protect form subsequent challenge with the virus (see column 17, in particular). The '504 also patent teaches administering MIMP as an adjuvant in combination with any commercially available vaccine for treating viral infection, including influenza virus (see columns 16, in particular, as well as columns 4, 12, and 14). The '504 patent teaches that said influenza vaccines can be ineffective alone (see column 4, in particular). Said vaccine for treating influenza virus can also be considered an "antiviral agent", a "microbial agent", or a "vaccine agent", as recited in the instant claims. The '504 patent also teaches administering MIMP in combination with various antibacterial and antifungal agents (i.e. "microbial agents", see column 16, in particular). Thus, the '504 patent teaches many embodiments that fall within the scope of the instant claims.

Applicant further argues that the '504 patent describes only a general T cell stimulation, and does not show a T cell response in influenza. Applicant concludes that without showing that IMP provides a T cell response specifically to influenza, the '504 patent does not disclose the method of the present invention.

The '504 patent teaches that after administration of viral vaccine combined with an IMP compound, proliferation assays in response to viral antigen can be performed in order to determine if the subject has been successfully immunized (see column 17, 5th full paragraph). It is well established that T cells proliferate in response to antigen stimulation in successfully immunized subjects, and the method disclosed by the '504 patent would inherently measure T cells proliferating specifically to the viral antigen.

3. The following are new grounds of rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24 is rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method of treating influenza comprising administering a protected IMP compound in combination with an antiviral agent, microbial agent, or vaccine agent, and detecting a "T cell response specific to influenza".

Applicant indicates that support for the new limitations of can be found in paragraph 68 and in Examples 2-4 of the specification.

A review of the specification fails to reveal support for the new limitations.

The specification in paragraph 68 discloses administering a vaccine composition for generating enhanced T cell immunity against infectious agents, such as influenza. In examples 2-4, the specification discloses administering a flu vaccine in combination with MIMP and measuring an influenza specific T cell response. However, the instant claims are not limited to administering an influenza vaccine in combination with MIMP and measuring a T cell response to influenza. Rather the claims broadly encompass administering MIMP with any vaccine agent, antiviral agent, or antimicrobial agent. For example, the claims specifically set forth that MIMP is administered in combination with parasite, for treating influenza and inducing influenza specific T cell responses. The specification does not disclose administering a parasite vaccine agent for treating influenza and for inducing detectable influenza specific T cell responses, as claimed.

Furthermore, the specification only discloses measuring influenza T cell responses after administration of an influenza vaccine and does not disclose measuring a T cell response to influenza after administration of an anti-viral agent or microbial agent.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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